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Laura Howard, Secretary Laura Kelly, Governor

## KANSAS DEPARTMENT FOR AGING AND DISABILITY SERVICES COVID-19 GUIDANCE

**DATE:** June 3, 2021

TO: State & Local Officials, Adult Care Home Operators/Owners/Administrators,

Stakeholders, Industry Associations, General Public

FROM: Secretary Laura Howard

SUBJECT: COVID-19 Testing Guidance for Adult Care Homes

**EFFECTIVE:** Immediatley

On August 25, 2020, CMS published an interim final rule with comment period (IFC), CMS3401-IFC, entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency". CMS recommends's recommends testing with authorized nucleic acid or antigen detection assays as an important addition to other infection prevention and control (IPC) recommendations aimed at preventing COVID-19 from entering nursing homes and other adult care home settings, detecting cases quickly, and stopping transmission. Swift identification of confirmed COVID-19 cases allows the facility to take immediate action to remove exposure risks to adult care home residents and staff. CMS has added 42 CFR § 483.80(h) which requires that the facility test all residents and staff for COVID-19 who are subject to federal regulations. Noncompliance related to this new requirement will be cited at new tag F886 for those Adult Care Homes that must comply with 42 CFR §483.80(h). KDADS is issuing this guidance for all Adult Care Homes identified in K.S.A. 39-923(a) subject to to the requirements of Kansas Exective Order 20-69).

#### **DEFINITIONS**

"Fully vaccinated" refers to a person who is  $\ge 2$  weeks following receipt of the second dose in a 2-dose series, or  $\ge 2$  weeks following receipt of one dose of a single-dose vaccine.

"Unvaccinated" refers to a person who does not fit the definition of "fully vaccinated," including people whose vaccination status is not known, for the purposes of this guidance.

#### **GUIDANCE**

#### **Testing of Adult Care Home Staff and Residents**

To enhance efforts to keep COVID-19 from entering and spreading through nursing homes, facilities are required to test residents and staff based on parameters and a frequency set by the HHS Secretary.

Facilities can meet the testing requirements through the use of rapid point-of-care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory. POC Testing is diagnostic testing that is performed at or near the site of resident care. For a facility to conduct these tests with their own staff and

equipment (including POC devices provided by the Department of Health and Human Services), the facility must have a CLIA Certificate of Waiver. Information on obtaining a CLIA Certificate of Waiver can be found here.

Facilities without the ability to conduct COVID-19 POC testing should have arrangements with a laboratory to conduct tests to meet these requirements. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.

"Facility staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff. We note that the facility may have a provision under its arrangement with a vendor or volunteer that requires them to be tested from another source (e.g., their employer or on their own). However, the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency, as described in Table 2 below.

Regardless of the frequency of testing being performed or the facility's COVID-19 status, the facility should continue to screen all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors, for signs and symptoms of COVID-19.

When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak (as specified below).

Testing Trigger	Staff	Residents
Symptomatic individual	Staff, Vaccinated and	Resident, Vaccinated and
identified	unvaccinated, with signs and	unvaccinated, with signs and
	symptoms must be tested	symptoms must be tested
Outbreak (Any new case	Test all staff, vaccinated and	Test all residents, vaccinated
arises in facility)	unvaccinated, that previously	and unvaccinated, that
	tested negative until no new	previously tested negative
	cases are identified*	until no new cases are
		identified*
Routine Testing	According to Table 2 below	Not recommended, unless the
		resident leaves the facility.

**Table 1: Testing Summary** 

\*For outbreak testing, all staff and residents should be tested, regardless of vaccination status, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. For more information, please review the section below titled, "Testing of Staff and Residents in Response to an Outbreak."

### Testing of Staff and Residents with COVID-19 Symptoms or Signs

Staff with symptoms or signs of COVID-19, vaccinated or not vaccinated, must be tested immediately and are

expected to be restricted from the facility pending the results of COVID-19 testing. If COVID-19 is confirmed, staff should follow Centers for Disease Control and Prevention (CDC) guidelines "<u>Criteria for Return to Work for Healthcare Personnel with SARSCoV2 Infection</u>." Staff who do not test positive for COVID-19 but have symptoms should follow facility policies to determine when they can return to work.

Residents who have signs or symptoms of COVID-19, vaccinated or not vaccinated, must be tested immediately. While test results are pending, residents with signs or symptoms should be placed on <u>transmission-based precautions (TBP) in accordance with CDC guidance</u>. Once test results are obtained, the facility must take the appropriate actions based on the results.

## **Testing of Staff and Residents with an Exposure**

For information on testing staff and resident who may have been exposed to COVID-19, see the <u>CDC's</u> <u>Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19</u> Vaccination.

#### Testing of Staff and Residents in Response to an Outbreak

An outbreak is defined as a new COVID-19 infection in any healthcare personnel (HCP) or any nursing home-onset COVID-19 infection in a resident. In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission. A resident who is admitted to the facility with COVID-19 does not constitute a facility outbreak.

Upon identification of a single new case of COVID-19 infection in any staff or resident, all staff and residents, regardless of vaccination status, should be tested immediately. All staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. See CDC guidance "Testing Guidelines for Nursing Homes" section Non-diagnostic testing of asymptomatic residents without known or suspected exposure to an individual infected with SARS-CoV-2.

For individuals who test positive for COVID-19, repeat testing is not recommended. A symptom-based strategy is intended to replace the need for repeated testing. Facilities should follow the <u>CDC guidance</u> <u>Discontinuation of Transmission-Based Precautions and Disposition of Patients with SARS-CoV-2 Infection in Healthcare Settings for residents and Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection.</u>

## **Routine Testing of Staff**

Routine testing of unvaccinated staff should be based on the extent of the virus in the community. Fully vaccinated staff do not have to be routinely tested. Facilities should use their county positivity rate in the prior week as the trigger for staff testing frequency. Reports of COVID-19 county positivity data can be located on the Kansas Department of Health and Environment webpage under Nursing Home Metrics (<a href="https://www.coronavirus.kdheks.gov/160/COVID-19-in-Kansas">https://www.coronavirus.kdheks.gov/160/COVID-19-in-Kansas</a>) or the color-coded positivity classification, which can be found on the <a href="https://www.coronavirus.kdheks.gov/160/COVID-19-in-Kansas">COVID-19 Nursing Home Data site</a>. Regardless of source facilities should remain consistent in which source their facility is utilizing.

- +Vaccinated staff do not need be routinely tested.
- \*This frequency presumes availability of Point of Care testing on-site at the adult care home or where off-site testing turnaround time is <48 hours.

If the 48-hour turn-around time cannot be met due to community testing supply shortages, limited access or inability of laboratories to process tests within 48 hours, the facility should document its efforts to obtain quick turnaround test results with the identified laboratory or laboratories and contact with the local and state health departments.

The facility should test all unvaccinated staff at the frequency prescribed in the Routine Testing table based on the county positivity rate reported in the past week. Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust the frequency of performing staff testing according to the table above.

- If the county positivity rate increases to a higher level of activity, the facility should begin testing staff at the frequency shown in the table above as soon as the criteria for the higher activity are met.
- If the county positivity rate decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the county positivity rate has remained at the lower activity level for at least two weeks before reducing testing frequency.

The guidance above represents the minimum testing expected. Facilities may consider other factors, such as the positivity rate in an adjacent (i.e., neighboring) county to test at a frequency that is higher than required. For example, if a facility in a county with low a positivity rate has many staff that live in a county with a medium positivity rate, the facility should consider testing based on the higher positivity rate (in scenario described, weekly staff testing would be indicated).

State and local officials may also direct facilities to monitor other factors that increase the risk for COVID-19 transmission, such as rates of <u>Emergency Department visits of individuals with COVID-19-like symptoms</u>. Facilities should consult with state and local officials on these factors, and the actions that should be taken to reduce the spread of the virus.

NOTE: Routine testing of asymptomatic residents is not recommended unless prompted by a change in circumstances, such as the identification of a confirmed COVID-19 case in the facility. Facilities may consider testing asymptomatic residents who leave the facility frequently, such as for dialysis or chemotherapy. Facilities should inform resident transportation services (such as non-emergency medical transportation) and receiving healthcare providers (such as hospitals) regarding a resident's COVID-19 status to ensure appropriate infection control precautions are followed.

### **Refusal of Testing**

Facilities must have procedures in place to address staff who refuse testing. Procedures should ensure that staff who have signs or symptoms of COVID-19 and refuse testing are prohibited from entering the building until the return to work criteria are met. If outbreak testing has been triggered and a staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed. The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic staff who refuse routine testing.

Residents (or resident representatives) may exercise their right to decline COVID-19 testing in accordance with the requirements under 42 CFR § 483.10(c)(6). In discussing testing with residents, staff should use person-centered approaches when explaining the importance of testing for COVID-19. Facilities must have procedures in place to address residents who refuse testing. Procedures should ensure that residents who have signs or symptoms of COVID-19 and refuse testing are placed on TBP until the criteria for discontinuing TBP have been met. If outbreak testing has been triggered and an asymptomatic resident refuses testing, the facility

should be extremely vigilant, such as through additional monitoring, to ensure the resident maintains appropriate distance from other residents, wears a face covering, and practices effective hand hygiene until the procedures for outbreak testing have been completed.

Clinical discussions about testing may include alternative specimen collection sources that may be more acceptable to residents than nasopharyngeal swabs (e.g., anterior nares). Providing information about the method of testing and reason for pursuing testing may facilitate discussions with residents or resident representatives.

If a resident has symptoms consistent with COVID-19 or has been exposed to COVID-19, or if there is a facility outbreak and the resident declines testing, he or she should be placed on or remain on TBP until he or she meets the symptom-based criteria for discontinuation.

# **Other Testing Considerations**

In keeping with current CDC recommendations staff and residents who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after symptom onset. Until more is known, testing should be encouraged again (e.g., in response to an exposure) 3 months after the date of symptom onset with the prior infection. Facilities should continue to monitor the CDC webpages and FAQs for the latest information. The facility should consult with infectious diseases specialists and public health authorities to review all available information (e.g., medical history, time from initial positive test, Reverse Transcription-Polymerase Chain Reaction Cycle Threshold (RT-PCR Ct) values, and presence of COVID-19 signs or symptoms). Individuals who are determined to be potentially infectious should undergo evaluation and remain isolated until they meet criteria for discontinuation of isolation or discontinuation of transmission-based precautions, depending on their circumstances.

For residents or staff who test positive, facilities should contact the appropriate state or local entity for contact tracing.

While not required, facilities may test residents' visitors to help facilitate visitation while also preventing the spread of COVID-19. Facilities should prioritize resident and staff testing and have adequate testing supplies to meet required testing, prior to testing resident visitors.

## **Conducting Testing**

In accordance with 42 CFR § 483.50(a)(2)(i), the facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with State law, including scope of practice laws to provide or obtain laboratory services for a resident, which includes COVID-19 testing (see F773). This may be accomplished through the use of physician approved policies (e.g., standing orders), or other means as specified by scope of practice laws and facility policy.

NOTE: Concerns related to orders for laboratory and/or POC testing should be investigated under F773.

Rapid POC Testing devices are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual.

Facilities must conduct testing according to nationally recognized guidelines, outlined by the Centers for Disease Control and Prevention (CDC). This would include the following guidelines:

- Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes.
- Testing Guidelines for Nursing Homes.
- Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2.

A diagnostic test shows if a patient has an active coronavirus infection. As of the date of this guidance, there are two types of diagnostic tests which detect the active virus – molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests that detect specific proteins on the surface of the virus. An antibody test looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. An antibody test does not identify an active coronavirus infection; therefore, conducting an antibody test on a staff or resident would not meet the requirements under this regulation.

When testing residents, a facility's selection of a test should be person-centered.

Collecting and handling specimens correctly and safely is imperative to ensure the accuracy of test results and prevent any unnecessary exposures. The specimen should be collected and, if necessary, stored in accordance with the manufacturer's instructions for use for the test and CDC guidelines.

During specimen collection, facilities must maintain proper infection control and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

The CDC has provided guidance on proper specimen collection:

- Influenza Specimen Collection.
- <u>Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).</u>
- CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).

For additional considerations for antigen testing, see CDC's Interim Guidance for Rapid Antigen Testing for RS-CoV-2. As a reminder, per 42 CFR § 483.50(a), the facility must provide or obtain laboratory services to meet the needs of its residents. If a facility provides its own laboratory services or performs any laboratory tests directly (e.g., SARS-CoV-2 point-of-care test) the provisions of 42 CFR Part 493 apply and the facility must have a current CLIA certificate appropriate for the level of testing performed within the facility. Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR Part 493.

### **Reporting Test Results**

Facilities conducting tests under a CLIA certificate of waiver are subject to regulations that require laboratories to report data for all testing completed, for each individual tested. For additional information on reporting requirements see:

- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes
- CMS memorandum: Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting
  of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA)
  Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public
  Health Emergency

Surveyors should report concerns related to CLIA certificates or laboratory reporting requirements to the CMS Division of Clinical Laboratory Improvement and Quality at LabExcellence@cms.hhs.gov. When reporting concerns include the CLIA number; name and address of laboratory (facility); number of days that results were not reported, if known; and number of results not reported, if known.

In addition to reporting in accordance with CLIA requirements, facilities must continue to report COVID-19 information to the CDC's National Healthcare Safety Network (NHSN), in accordance with 42 CFR § 483.80(g)(1)–(2). See "Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes," CMS Memorandum QSO-20-29-NH (Revised April 27, 2021).

All Adult Care Homes must satisfy the <u>Kansas public health requirements for reporting infectious disease</u> outbreaks.

NOTE: Concerns related to informing residents, their representatives and families of new or suspected cases of COVID-19 should be investigated under F885.

NOTE: Concerns related to the reporting to state and local public health authority of communicable diseases and outbreaks, including for purposes such as contact tracing, should be investigated under F880.

### **Documentation of Testing**

Facilities must demonstrate compliance with the testing requirements. To do so, facilities should do the following:

- For symptomatic residents and staff, document the date(s) and time(s) of the identification of signs or symptoms, when testing was conducted, when results were obtained, and the actions the facility took based on the results.
- Upon identification of a new COVID-19 case in the facility (i.e., outbreak), document the date the case was identified, the date that all other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests. All residents and staff that tested negative are expected to be retested until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result (see section Testing of Staff and Residents in response to an outbreak above).
- For staff routine testing, document the facility's county positivity rate, the corresponding testing frequency indicated (e.g., every other week), and the date each positivity rate was collected. Also, document the date(s) that testing was performed for all staff, and the results of each test.
- Document the facility's procedures for addressing residents and staff that refuse testing or are unable to be tested, and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.
- When necessary, such as in emergencies due to testing supply shortages, document that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Facilities may document the conducting of tests in a variety of ways, such as a log of county positivity rates, schedules of completed testing, and/or staff and resident records. However, the results of tests must be done in accordance with standards for protected health information. For residents, the facility must document testing results in the medical record. For staff, including individuals providing services under arrangement and volunteers, the facility must document testing results in a secure manner consistent with requirements

specified in 483.80(h)(3).

### **Surveying for Compliance**

Compliance will be assessed through the following process using the COVID-19 Focused Survey for Nursing Homes:

- 1. Surveyors will ask for the facility's documentation noted in the "Documentation of Testing" section above, and review the documentation for compliance.
- 2. Surveyors will also review records of those residents and staff selected as a sample as part of the survey process.
- 3. If possible, surveyors should observe how the facility conducts testing in real-time. In this process, surveyors will assess if the facility is conducting testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests, such as ensuring PPE is used correctly to prevent the transmission of the virus. If observation is not possible, surveyors should interview an individual responsible for testing and inquire on how testing is conducted (e.g., "what are the steps taken to conduct each test?").
- 4. If the facility has a shortage of testing supplies, or cannot obtain test results within 48 hours, the surveyor should ask for documentation that the facility contacted state and local health departments to assist with these issues.

Facilities that do not comply with the testing requirements in § 483.80(h) will be cited for noncompliance at F886. Additionally, enforcement remedies (such as civil money penalties) will be imposed based on the resident outcome (i.e., the scope and severity of the noncompliance), in accordance with Chapter 7 of the State Operations Manual.

If the facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the facility for noncompliance. Surveyors should also inform the state or local health authority of the facility's lack of resources.

CMS is also continuing to assess automated methods for determining compliance with the testing requirements, which may augment the assessment of compliance through onsite surveys.

#### Additional Resource Links:

- Clinical Questions about COVID-19: Questions and Answers-Testing in Nursing Homes <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes">https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes</a>
- Nursing Home Reopening Recommendations for State and Local Officials https://www.cms.gov/files/document/qso-20-30-nh.pdf-0
- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html</a>

### **COVID-19 Focused Survey for Nursing Homes**

CMS revised the COVID-19 Focused Survey for Nursing Homes tool to reflect the new testing requirements implemented in the IFC. The current Survey/Infection Prevention, Control & Immunization Pathway (CMS-20054) can be found in the LTC Survey Pathways zipfile located at https://www.cms.gov/Medicare/Provider-

Enrollment- and Certification/Guidance for Laws And Regulations/Downloads/LTC-Survey-Pathways. zip.

Contact: Questions related to the nursing home testing requirement may be submitted to: DNH\_TriageTeam@cms.hhs.gov.